Notice of Allowability	Application No.	Applicant(s)	
	10/524,787	EISENBACH ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the telephone interview of 10/14/10*.

2. ☒ The allowed claim(s) is/are *1,7,15-17,21-23,59 and 63-68*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *10/14/10* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Lynn Bristol/
Primary Examiner

DETAILED ACTION

1. Claims 1, 7, 15-17, 21-23, 59 and 63-68 are all the pending claims for this application.

2. Claims 3, 9, 14, and 37 were cancelled, Claims 1, 13, 30, 36, and 62 were amended and new Claims 65-68 were added in the Response of 2/1/10.

3. Claims 4-6, 12, 13, 24-30, 36, 38, 39, 43-46, 51-58, and 60-62 are cancelled and Claims 1, 7, 63 and 64 are amended by Examiner's Amendment set forth below.

4. Claims 1, 7, 15-17, 21-23, 59 and 63-68 are all the claims under examination.

Withdrawal of Objections

Claim Objections

5. The objection to the claims for improper spacing is withdraw.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph

6. The rejection of Claims 1, 4-7, 12, 13, 15-17, 21-23, and 62 for the recitation "human mRNA sequence gene" in Claim 1 because the identity of the gene is not ascertainable from the specification or the priority document is moot for the cancelled subject matter in Claim 1.

Applicants have agreed to the amendment of Claim 1 to delete the offending subject matter by Examiner's Amendment set forth below.

Claim Rejections - 35 USC § 112, first paragraph

Biological Deposit

7. The rejection of Claims 1, 4-7, 12, 13, 15-17, 21-23, and 62 under 35 U.S.C. § 112, first paragraph, because the specification does not enable a polynucleotide which comprises/encodes an mRNA and having the exact chemical identity of "the human mRNA gene sequence" of Claim 1 is withdrawn.

Applicants have agreed to the amendment of Claim 1 to delete the offending subject matter by Examiner's Amendment set forth below.

Written Description

8. The rejection of Claims 1, 4-6, 12, 13, 15-17, 21-23, 30, 36, 38, 39, 43-45, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims are drawn to an isolated tumor associated antigen (TAA) peptide of eight to ten amino acid residues, which is capable of promoting effective binding to a MHC class I molecule to elicit a CTL response and which is encoded by a polynucleotide overexpressed in human colon carcinoma cells, which polynucleotide is selected from the group consisting of human defensin 6 gene, human ADP/ATP translocase gene, human parathymosin gene, human I-8U interferon inducible gene, human chaperonin-like protein gene, human SPARC/osteonectin gene, human I-8D interferon inducible gene, human TB2 gene, human alpha-1 collagen gene, human mRNA for dipeptidase, fibronectin gene, actin binding protein gene, HCG IV mRNA, HLA-DR antigens associated invariant gamma chain gene, MHC class I HLA-

C.1 gene, polyA binding protein gene, transforming growth factor-beta induced gene, human mRNA for laminin-binding protein, human mRNA sequence gene, insulin like growth factor II gene, human ribosomal protein L23a mRNA, human acidic ribosomal phosphoprotein P1 gene, human liver mRNA fragment DNA binding protein UPI gene, ribosomal protein L37 gene, human MHC protein homologous to chicken B complex gene and HB23 gene for B23 nucleophosmin, wherein said peptide optionally includes one amino acid substitution is withdrawn.

Applicants have agreed to the amendment of Claim 1 to delete the offending subject matter and to the further amendment of the claims to recite specific peptides in a Markush group format by Examiner's Amendment set forth below.

EXAMINER'S AMENDMENT

9. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allen Yun on 10/14/10.

The application has been amended as follows:

1. (Currently Amended) An isolated tumor associated antigen (TAA) peptide of eight to ten amino acid residues, which is capable of promoting effective binding to a MHC class I molecule to elicit a CTL response and which is encoded by a

polynucleotide overexpressed in human colon carcinoma cells, ~~which polynucleotide is selected from the group consisting of human defensin 6 gene, human ADP/ATP translocase gene, human parathymosin gene, human I-8U interferon inducible gene, human chaperonin-like protein gene, human SPARC/osteonectin gene, human I-8D interferon inducible gene, human TB2 gene, human alpha-1 collagen gene, human mRNA for dipeptidase, fibronectin gene, actin binding protein gene, HCG IV mRNA, HLA-DR antigens associated invariant gamma chain gene, MHC class I HLA-C.1 gene, polyA binding protein gene, transforming growth factor-beta induced gene, human mRNA for laminin-binding protein, human mRNA sequence gene, insulin like growth factor II gene, human ribosomal protein L23a mRNA, human acidic ribosomal phosphoprotein P1 gene, human liver mRNA fragment DNA binding protein UPI gene, ribosomal protein L37 gene, human MHC protein homologous to chicken B complex gene and HB23 gene for B23 nucleophosmin,~~

~~wherein said peptide optionally includes one amino acid substitution~~ selected from the group consisting of the amino acid sequence of SEQ ID NO:27, SEQ ID NO:11; SEQ ID NO:25, SEQ ID NO:16, SEQ ID NO:20, SEQ ID NO:21 and SEQ ID NO:22.

Claim 4-6 (Cancelled).

Claim 7 (Currently amended) The peptide of claim ~~4~~ 1 which has the amino acid sequence of SEQ ID NO:27.

Claim 12, 13, 24-30, 36, 38, 39, 43-46, 51-58, and 60-62 (Cancelled).

Claim 63 (Currently amended) The peptide of claim 4- 1 which has the amino acid sequence of SEQ ID NO:11.

Claim 64 (Currently amended) The peptide of claim 4- 1 which has the amino acid sequence of SEQ ID NO:25.

Examiner's Statement of Reasons for Allowance

10. The following is an examiner's statement of reasons for allowance: peptide 3-7 (peptide of SEQ ID NO: 27 from 1-8D interferon inducible gene protein), peptide 1-6 (peptide of SEQ ID NO: 11 from 1-8D interferon inducible gene protein), and peptide 3-5 (peptide of SEQ ID NO: 25 from 1-8D interferon inducible gene protein) have been tested in vitro and in vivo experiments with results shown in Figures 4-10. The peptide 1-11 (peptide of SEQ ID NO: 16 from actin binding protein); peptide 2-3 (peptide of SEQ ID NO: 20 from human ribosomal protein L23a); peptide 3-1 (peptide of SEQ ID NO: 21 from TGF beta induced gene); and peptide 3-2 (peptide of SEQ ID NO: 22 from human TB2 gene) have been tested in vitro and shown to be immunogenic (Table 3).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

11. Claims 1, 7, 15-17, 21-23, 59 and 63-68 are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNN BRISTOL whose telephone number is (571)272-6883. The examiner can normally be reached on 8:00-4:30, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Primary Examiner, Art Unit 1643